

UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA

In re: BAIR HUGGER FORCED AIR  
WARMING DEVICES PRODUCTS  
LIABILITY LITIGATION

MDL No. 15-2666 (JNE/FLN)

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This Document Relates To:  
*All Cases*

**PLAINTIFFS' REPLY IN  
SUPPORT OF MOTION TO  
EXCLUDE THE TESTIMONY  
OF THEODORE HOLFORD  
AND JONATHAN BORAK  
UNDER FED. R. EVID. 702-703**

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**INTRODUCTION**

In Plaintiffs' opening memoranda to exclude the testimony of Holford and Borak, Plaintiffs argued and put forth evidence that the opinions of both experts were untethered to any recognized scientific methodology. Relying on incomplete and unreliable draft datasets to speculate about supposed tabulation errors in the McGovern study, all the way to their failure to follow the most basic methods of identifying confounding variables, Holford and Borak do nothing more than parrot the unscientific arguments of Defendants.

Unable to soften the blow of the admissions that Holford and Borak gave up in their depositions, Defendants turn a blind eye to that sworn testimony and instead throw a "Hail Mary." Raising numerous new documents that were never mentioned or cited by either expert, Defendants desperately scramble to backfill the *ipse dixit* of Holford and Borak. Their last minute attempt to shield Holford and Borak is not only procedurally improper, but their *ex post facto* reliance on newly cited evidence showcases the unreliability of Holford's and Borak's opinions under the Federal and Minnesota Rules of Civil Procedure.

## **ARGUMENT**

### **I. DEFENDANTS CANNOT BACKFILL THE UNRELIABLE *IPSE DIXIT* OF HOLFORD AND BORAK BASED ON NEWLY CITED EVIDENCE**

In their ongoing campaign to vilify the McGovern study, Defendants rely on 35 exhibits to support Holford’s and Borak’s opinion that the study provides no evidence of causation. Glaringly, many of these exhibits—ranging from the 2016 Brimmo study to the expert report of Dr. Michael Mont—were not cited by either expert in their reports or discussed at their depositions. Defendants’ eleventh-hour attempt to bolster Holford’s and Borak’s unreliable testimony with new exhibits violates the Federal Rules of Evidence.

#### **A. Testimony Based on Undisclosed Evidence Violates Rules 702 and 703.**

Rule 703 limits the bases of an expert’s opinion to “facts or data in the case that the expert has been *made aware of or personally observed*,” as long as other experts in the field would reasonably rely on that evidence in forming an opinion. *Id.* (emphasis added).

Because Holford and Borak were not aware of the new exhibits, Rule 703 bars both experts from relying on them. The purpose for which Defendants offer this evidence also violates the reliability requirements of Rule 702. While Holford and Borak never relied on the exhibits, Defendants impute knowledge of their contents to both experts in order to make hearsay arguments and to establish a basis for their opinions when there was none.

Defendants thus lay bear their strategy to use Holford and Borak as ventriloquists for their own advocacy instead of scientifically supported opinions, ultimately ignoring that expert testimony must be based on “more than subjective belief or unsupported speculation.” *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 590 (1993). Testimony

unhinged from facts is not only unreliable, *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146–47 (1997), it is irrelevant. *See, e.g., U.S. v. Stone*, 222 F.R.D. 334, 341 (E.D. Tenn. 2004) (declaring that experts may not serve as mouthpieces through which hearsay is presented).

## **II. HOLFORD CONCEDES THAT HIS CALCULATIONS ARE UNRELIABLE**

### **A. Defendants Do Not Dispute That Holford’s Analysis Contains Fatal Flaws.**

Defendants’ response to Plaintiffs’ motion to exclude the testimony of Holford is more notable for what it does *not* say than what it actually does say. Plaintiffs’ opening memorandum attacked the entirety of Holford’s testimony, Dkt. No. 802, including the following topics: (1) reclassification of infection data, *id.* at 8–12; (2) competing statistical tests, *id.* at 12–17; (3) hospital infection rates and time trends, *id.* at 17–19; (4) start dates, *id.* at 20–21; (5) confounding factors, *id.* at 21–30; and (6) causation findings, *id.* at 30–32. Given the strength of Plaintiffs’ challenges, Defendants have not even addressed—much less rebutted—the overwhelming majority of these arguments. *See* Dkt. No. 913 at 9–36.

#### *1. Defendants do not dispute the unreliability of Holford’s unscientific use of different statistical tests to artificially dilute the McGovern study.*

Holford needlessly and selectively applied a different statistical test to artificially dilute the strength of the McGovern study. *See* Dkt. No. 802 at 12–14. Instead of applying Chi-Squared to his remixed dataset, which would have *still shown a significant difference* in infection rates, Holford used the “overly conservative” Fisher’s test, which allowed him to calculate a barely non-significant difference ( $p=0.0507$ ). Ex.C, Holford Rpt. at 2; *see*

*also* Ex.D, Holford Dep. at 182:13–186:18.<sup>1</sup> His reason for doing so rested not on sound science but rather on his “own bias.” *Id.* at 204:5–25. He “followed [his] own rule of thumb” and disregarded his practice outside the courtroom where he applies Chi-Squared to similar and smaller datasets. *See* Ex.K, Holford (2002); *see also* Ex.L, Holford (2009).

In fact, while Holford initially relied on Fisher’s test to demonstrate an alleged lack of statistical significance with respect to the infection data in the McGovern study, he later reversed course and applied the “the same chi-square method” as used by the study authors. Ex.C, Holford Rpt. at 4–5; Dkt. No. 913 at 29. Flip-flopping between tests simply to show an alleged lack of statistical significance reflects litigation bias, not sound science. In other words, as Defendants put it, it was not hard for Holford to show non-significant results when he shot his arrow first and then painted his own target around the arrow. *Id.* at 30.

For that reason, Defendants do not even try to save Holford’s attempt to dilute the significance of the study he was hired to attack; however, they do wrongly suggest that Plaintiffs cannot prove causation without the McGovern study itself. Dkt. No. 913 at 7; *cf.* *Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 992 (8th Cir. 2001). The Court should thus exclude Holford’s “results driven” reanalysis. Ex.C, Holford Rpt. at 2–3; *see also In re Lipitor Prod. Liab. Litig.*, 145 F. Supp. 3d 573, 583 (D.S.C. 2015) (excluding statistician who engaged in “results driven” science by using different tests to generate desired results).

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<sup>1</sup> Unless otherwise designated herein, Plaintiffs rely on the same exhibits cited in support of their opening memorandum to exclude the testimony of Holford. *See, e.g.*, Dkt. No. 807.

2. *Defendants do not dispute the unreliability of Holford's testimony regarding hospital infection rates and corresponding time trend data.*

Holford also distorted hospital infection rates and time trend data. *See* Dkt. No. 802 at 17. His sworn deposition testimony reveals that he not only compared apples to oranges by contrasting infection rates during different time periods, but Dr. Reed's testimony and Defendants' own documents readily unveil that infection data from other hospitals are unrealistically low and that the infection rate at Wansbeck Hospital was actually *lower* than most hospitals. *See* Ex.G, Reed Dep. at 67:9–15; *see also* Ex.P, Van Duren Dep. Ex. 77.

Stuck with Holford's admission that he did not “know the degree of accuracy” of his calculations or that he did not use a recognized scientific method in splicing infection data, Defendants have not responded to *any* of Plaintiffs' arguments. The Court should thus exclude Holford's opinions regarding hospital infection rates and time trend data. Ex.C, Holford Rpt. at 3–4; *see also* *Lewis v. PDV Am., Inc.*, 532 F. Supp. 2d 1006, 1009 (N.D. Ill. 2008) (excluding expert due to party's failure to oppose); *McClure v. Greater San Antonio Transportation Co.*, 2008 WL 11335001, at \*7 (W.D. Tex. Oct. 3, 2008) (similar).

3. *Defendants do not dispute the unreliability of Holford's speculation that surgical site infection interventions confounded the McGovern study.*

Tellingly, Defendants say nary a word about Holford's opinion on surgical site infection (SSI) interventions. Dkt. No. 802 at 21. Nor could they. Plaintiffs made clear that Holford did not cite a *single* study showing an association between SSI interventions and deep joint infection (DJI). *Id.* at 22. Holford admitted so on cross-examination, stating that he had “no scientific basis or expertise” to conclude that SSI measures impacted DJI. Ex.D, Holford Dep. at 306:17-308:14. Because Defendants cannot shore up Holford's *ipse dixit*,

it founders on the shoals of his own testimony. The Court should therefore bar Holford's opinion as to the alleged impact of SSI measures on DJI rates. Ex.C, Holford Rpt. at 4, 9.

4. *Defendants do not dispute the unreliability of Holford's attempt to opine on general causation based on statistical calculations alone.*

Finally, Holford should not be allowed to opine on general causation. Dkt. No. 802 at 30. Holford limited his analysis to statistics even though he admitted that evaluating causation "is not a matter of statistics alone." Ex.D, Holford Dep. at 374:7-376:10. Given that Holford "leaves it to others to discuss this evidence further," Ex.C, Holford Rpt. at 9, it's no wonder that Defendants have not tried to rescue his so-called "causation findings." *Id.* at 7-10. In fact, based on Holford's sworn admissions in this litigation, Defendants have now accepted that Holford's opinion should be "limited to his biostatistical analysis." *See* Dkt. No. 913 at 47. The Court should follow suit and exclude his causation testimony. *Id.*

**B. Holford Used Unreliable Data to Retabulate the Published Raw Data.**

Unlike the prior topics of testimony, Defendants at least attempt to address the first topic regarding Holford's reclassification of infection data. *See* Dkt. No. 913 at 10-18. Despite the factual errors that riddle their theory, Defendants' attempt to save Holford's tabulation error theory is much more notable for what it does *not* say than what it does say.

1. *Holford's opinion is unsound because he relies on data which he admits is incomplete and contradicts the raw case data in the McGovern study.*

Not a *single* sentence of Defendants' argument addresses the most untrustworthy aspects of Holford's testimony. Holford swore under oath that he did *not* know whether the dataset he used to perform his statistical calculations was the same dataset used by the authors of the McGovern study. Ex.D, Holford Dep. at 121:24-122:24, 127:22-130:10,

144:15-148:7, 155:8–11, 168:15-170:15, 172:2–24. He also confessed that the dataset he did use to perform his calculations was *incomplete* and *did not match* the raw data in Figure 7 of the study. *Id.* at 168:22-170:14, 173:5-174:25. Low and behold the following colloquy:

Q. Mr. Gordon [3M’s counsel] doesn’t know if Exhibit 10 is the original data set.

A. Okay.

Q. Mr. Albrecht [coauthor of the McGovern study] doesn’t know whether Exhibit 10 is the original data set.

A. Yeah.

Q. Mr. Borak [Defendants’ medical expert] also doesn’t know whether Exhibit 10 is the original data set.

A. Okay.

**Q. And you don’t know.**

**A. I don’t.**

Ex.D, Holford Dep. at 128:21-129:6 (emphasis added).

Although Holford did not know whether Exhibit 10 contained the same dataset used by the authors of the McGovern study, he knew that it was *incomplete* and *inconsistent* with the final raw data published in Figure 7 of the study. Indeed, Holford learned for the *first time* at his deposition that Exhibit 10 was *missing an entire page of data* corresponding to the exact same timeframe when the study reported infections attributable to Bair Hugger. *Id.* at 111:2–4 (“I didn’t see that there was a – a – a – miss – a missing page in the – in the data set that I used to analyze.”). Holford therefore conceded that he did not “recall going over all of the details in [Exhibit 10] and seeing [the] missing [data].” *Id.* at 110:19–22.

Nor did Holford “shuffl[e] through by hand everything [in Exhibit 10] to [do] the tabulation.” *Id.* at 113:9–16. He just relied on what Defendants spoon-fed him. *Id.* at 94:10–12 (admitting “no independent investigation outside of what was provided to [him]”); *see also In re TMI Litig.*, 193 F.3d 613, 705 (3d Cir. 1999) (excluding expert for same reason); *In re Titanium Dioxide Litig.*, 2013 WL 1855980, at \*9 (D. Md. May 1, 2013) (similar).

While those facts alone doom his opinion, Holford also admitted that the dataset he used *omitted* final data reflected in the McGovern study. Figure 7 of the study shows “raw case data” regarding each infection that occurred during the study. Ex.B at 1543. In other words, the McGovern study itself reflects the final data. Moreover, unlike the incomplete data used by Holford, which included only 31 Bair Hugger infections, the “raw case data” reported in McGovern reveals *32 infections*—the *identical* number of infections the authors used to find that Bair Hugger significantly increases the risk of DJI. *Id.* at 1542. Holford not only admitted that fact, Ex.D, Holford Dep. at 170:12–15, but he conceded that the incomplete dataset he used did *not* account for at least one of the final data points. *Id.* at 168:18–21. Per Holford, this creates “a problem with [his] analysis.” *Id.* at 128:12–129:20.

The Supreme Court has instructed that expert statistics are unreliable if they derive from “incomplete data sets and inadequate statistical techniques.” *Watson v. Fort Worth Bank and Trust*, 487 U.S. 977, 996–97 (1988). The REFERENCE MANUAL echoes the same teaching, warning that “flaws in the data can undermine any statistical analysis,” no matter how qualified an expert may be. REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 216 (3d ed. 2011). Federal courts follow these instructions and exclude expert testimony where, as



here, an expert attempts to spin straw into gold by relying on incomplete or unreliable data.<sup>2</sup> This Court should follow suit and exclude Holford's unreliable theory of a tabulation error.

**C. Defendants' Supplemental Evidence Does Not Rehabilitate Holford.**

Stuck between a rock and a hard place, Defendants do not even attempt to address Holford's fatal admissions; instead, they paper-over his sworn testimony with a string of supplemental sources never mentioned or cited in his expert report. Dkt. No. 913 at 10–18.

Reliance on these exhibits at this late juncture is not only improper, *see, e.g.*, Fed. R. Civ. P. 703, but as explained *infra*, none of Defendants' *ex post facto* arguments actually shield Holford's testimony. The fact therefore remains that Holford relied on an incomplete and incorrect dataset, rendering *all* of his opinions unreliable. Ex.C, Holford Rpt. at 2–3; *see also* Ex.D, Holford Dep. at 173:13-174:25 (all his calculations depend on Exhibit 10).

*1. Defendants blithely ignore the raw data published in Figure 7 along with their failure to obtain discovery from the only custodian of the data.*

As a threshold matter, none of Defendants' belated arguments rescue Holford because they all *ignore* the fact that Figure 7 of the McGovern study reflects the *final raw data* underlying the number of infections reported in the study. Ex.B at 1543. The “raw case data” depicted therein specify whether or not a DJI occurred, and, if so, the month and

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<sup>2</sup> *See Montgomery Cty. v. Microvote Corp.*, 320 F.3d 440, 449 (3d Cir. 2003) (excluding expert based on incomplete data); *Viterbo v. Dow Chem.*, 826 F.2d 420, 423 (5th Cir.1987); *Bruno v. Bozzuto*, 311 F.R.D. 124, 143 (M.D. Pa. 2015); *In re Lipitor Prod. Liab. Litig.*, 145 F. Supp. 3d 573, 582 (D.S.C. 2015); *EEOC v. Freeman*, 961 F. Supp. 2d 783, 792–95 (D. Md. 2013); *Malletier v. Dooney & Bourke*, 525 F. Supp. 2d 558, 630 (S.D.N.Y. 2007); *North v. Ford Motor Co.*, 505 F. Supp. 2d 1113, 1119 (D. Utah 2007) (same); *see also In re Polypropylene Carpet Antitrust Litig.*, 93 F. Supp. 2d 1348, 1355 (N.D. Ga. 2000) (declaring that expert “opinions based upon erroneous data, of course, must be excluded”).

year of infection. *Id.* at 1543. Given these data, Figure 7 *proves* that 32 infections occurred during the “forced air” period and 3 infections occurred during the “conductive” period—the same number of infections as reported in the study. *Id.* at 1542–43. Any “draft” data or other half-baked evidence relied upon by Defendants is thus *irrelevant*. Dkt. No. 913 at 32.

The frivolity of Defendants’ arguments is also evident from their failure to obtain discovery from the *only* custodian of the dataset. Dr. McGovern testified that although he and Dr. Reed both worked at Wansbeck, he was not responsible for collecting infection data, leaving that task to Dr. Reed. Ex.EE, McGovern Dep. at 357:6–14. Dr. Reed likewise testified that he and a team of nurses had collected all the data. Ex.G, Reed Dep. at 46:11–20; Ex.FF, Reed Dep. at 51:20–52:2. Defendants admit as much in their opposition brief. *See* Dkt. No. 913 at 11 (citing DX9, Reed Dep. at 53:10–13) (“I would have provided it.”).

Though Defendants were well aware that Dr. Reed was the *only* custodian of the data, they never obtained discovery from him in glaring contrast to their assertion that they “aggressively pursued *every* potential source of information.” Dkt. No. 913 at 10. Even worse, Defendants tout Exhibit 10 even though Holford and Borak do *not* know whether it contains the final data, Ex.D, Holford Dep. at 128:21–129:6, and even though the authors testified that it is *not* the final data, *see, e.g.*, Ex.E, Albrecht Dep. at 150:21–151:2. Absent any foundation to rely on Exhibit 10, Holford cannot turn a sow’s ear into a silk purse.

Attempting to rationalize Holford’s reliance on Exhibit 10, Defendants aver that Mr. Albrecht’s testimony proves that “the dataset produced by Augustine was the only complete set of McGovern infection data produced in this litigation.” Dkt. No. 913 at 10 (citing DX13, Albrecht Dep. at 150:4–151:3). The citation shows no such thing. Albrecht

*never* testified that Dr. Augustine possessed the final dataset; he said that he “did not have the exact data in front of [him] that was used” in the study and that defense counsel had instead “given him this table [Exhibit 10] telling [him] that it is” the final data. *Id.* Albrecht’s true testimony thus turns Defendants’ argument on its head and unveils that Defendants will even mispresent the record to salvage Holford’s untrustworthy opinion.

2. *Defendants’ assertions (ad seriatim) are belied by the factual record.*

The remaining five points raised by Defendants fare no better. Dkt. No. 913 at 11–13. Without any explanation whatsoever, Defendants say that “except for the tabulation error identified by Holford, the data produced by Augustine correspond exactly to the representations about the data in the published study.” *Id.* at 11. The meaning of this assertion is far from clear, but the fact remains that Holford admitted that Exhibit 10, which contains the “data produced by Augustine,” was incomplete and did not account for the “raw case data” reported in the McGovern study. *See* Ex.D, Holford Dep. at 110:19–111:4 (missing page of data); *see also id.* at 168:18–21 (missing data that was reported in study).

Defendants also rely on Dr. Reed’s deposition, but his testimony proves that the dataset Holford relied on was not the “real” thing. Dkt. No. 913 at 11. Consistent with Plaintiffs’ argument, the testimony shows that Dr. Reed, not Dr. Augustine, would have collected and “provided” the underlying data to the study authors, which was ultimately published in Figure 7 of the McGovern study. *Id.* (citing DX9, Reed Dep. at 53:10–13). The testimony also shows that Dr. Reed “d[i]dn’t know if [Exhibit 10] was what [he] gave” the study authors. *See id.* at 12 (citing DX9, Reed Dep. at 53:24–25). And finally, the testimony shows that Dr. Reed did not know whether or not the incomplete data contained

in Exhibit 10 were “accurate.” *See id.* at 12 (citing DX9, Reed Dep. at 54:3–4). Defendants’ backdoor reliance on Dr. Reed’s sworn testimony therefore hurts, not helps, their argument.

Defendants’ invocation of Mr. Albrecht’s deposition testimony meets the same fate. Dkt. No. 913 at 12. Besides ignoring his testimony that the McGovern study does *not* contain an alleged tabulation error, Ex.E, Albrecht Dep. at 158:21–25, 163:22–24, 167:25–168:12, Defendants badly distort Albrecht’s testimony. He *never* testified that the data contained in Exhibit 10 “were probably the updated data” or that those data “supported a lower odds ratio than the published study.” Dkt. No. 913 at 12. The cited testimony instead shows that he was referring to a “new file” that had nothing to do with the same cohort of patients analyzed in the McGovern study. *Id.* (citing DX13, Albrecht Dep. at 163:8–24).

In fact, the “private” email referred to but not cited by Defendants reveals that Dr. Reed had asked Albrecht to review an entirely different cohort based on “further infection data,” “new dates,” and “different reporting practices.” DX17 (Albrecht Ex. 12). To put the dispute to bed, Dr. Reed even stated that “[t]he original file [he] sent for the paper was definitely correct” and that he “checked it multiple times” before publication. *Id.* The testimony cited by Defendants therefore *disproves* their mangled factual arguments. *Id.*

Defendants’ “fourth” attempt to rescue Holford is just as unavailing as each and every one of their prior arguments. *See* Dkt. No. 913 at 12–13. Defendants not only cite Dr. Reed’s testimony to claim that *he* was responsible for collecting infection data, *id.* at 11 (“I would have provided it.”), but they revert to a spreadsheet of data produced by Dr. McGovern to speculate about an alleged inconsistency. *Id.* at 12 (citing DX15). Defendants declare that Dr. McGovern “agreed” that the spreadsheet he produced matches the data

presented in Exhibit 10 because both spreadsheets contain “31” Bair Hugger infections and “4” HotDog infections—one less infection for Bair Hugger and one more infection for HotDog than reported in the study. *Id.* at 13. *False.* Elementary arithmetic shows 32 “FAW” and 3 “CWB” infections in the table produced by Dr. McGovern. DX15. For that very reason, he agreed that the “spreadsheet he produced matched the data presented in the published study.” *Cf.* Dkt. No. 913 at 13 (citing DX16, McGovern Dep. II at 371:3–6).

Defendants’ fifth argument proves the same point. Defendants emphasize that Plaintiffs told the Court that Dr. Samet had reviewed “all the evidence, all the underlying raw data, and concluded that McGovern is absolutely a valid study.” Dkt. No. 913 at 13. To be sure, Dr. Samet reviewed almost *200 data sources*, ranging from the deposition transcripts and exhibits of the study authors, to a multitude of documents produced by Defendants and the authors, and he concluded that McGovern *is* a valid study. *See* Dkt. No. 910-54 at 1–15. Dr. Samet also relied on the final and complete “raw case data” reported in Figure 7 of the McGovern study, which *perfectly* aligns with the increased risk of infection reported in the study. Because Exhibit 10 is not the “real” data, any attempt to malign Plaintiffs based on Dr. Samet’s alleged failure to review an unreliable dataset falls flat. So too does Defendants’ dubious assertion that Plaintiffs should have sought discovery from Dr. Augustine, who was never involved in collecting the data. *Cf.* Dkt. No. 913 at 13.

### 3. *McGovern Exhibit 16 does not save Holford from exclusion.*

Defendants also attempt to redeem Holford based on a draft spreadsheet produced by Dr. McGovern, otherwise known as “McGovern Exhibit 16.” Although Defendants admit that the spreadsheet contains 32 Bair Hugger (“FAW”) infections and 3 HotDog

(“CWB”) infections, they “suggest” that one FAW infection was “apparently” miscoded since it occurred on September 15, 2010, during the CWB period. Dkt. No. 913 at 14–15.

At best, this “suggestion” is sheer speculation; at worst, the “apparent” argument belies Holford’s own sworn testimony. When pressed on the same surmise that Defendants raise here, Holford quickly distanced himself from McGovern Exhibit 16, confessing that he “didn’t know” whether the September 15 infection had been simply miscoded as to the date of infection instead of the type of warming device. Ex.D, Holford Dep. at 155:8–11. Like Defendants, he just assumed so, vitiating the reliability of his “expert” testimony.<sup>3</sup> *Id.*

What’s more, Holford admitted that McGovern Exhibit 16 conflicted with the final data reported in Figure 7 of the published study. He first agreed that Figure 7 contained “an additional jittered data point in the 2008 Bair Hugger period that is not reflected on McGovern 16.” *Id.* at 169:4–7. He then conceded that McGovern Exhibit 16 was *missing* infection data from Figure 7 that would have otherwise corroborated the occurrence of 32 rather than 31 infections during the FAW period.<sup>4</sup> *Id.* at 170:8–16. Defendants’ failure to cite a single word of Holford’s testimony on this point is telling; it exposes Defendants’

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<sup>3</sup> See, e.g., *United States v. Bailey*, 571 F.3d 791, 803 (8th Cir. 2009) (“Expert evidence is unreliable if it is speculative, unsupported by sufficient facts, or contrary to the facts of the case.”); *J.B. Hunt Transport, Inc. v. General Motors Corp.*, 243 F.3d 441, 444 (8th Cir. 2001); *Children’s Broad. Corp. v. Walt Disney Co.*, 245 F.3d 1008, 1018 (8th Cir. 2001); *Weisgram v. Marley Co.*, 169 F.3d 514, 520 (8th Cir. 1999), *aff’d*, 528 U.S. 440 (2000); *Grp. Health Plan, Inc. v. Philip Morris, Inc.*, 188 F. Supp. 2d 1122, 1131 (D. Minn. 2002).

<sup>4</sup> Because Dr. McGovern did not collect the data, see Ex.EE, McGovern Dep. at 357:6–14, his reluctance to testify about the exhibit does not help Defendants. Cf. Dkt. No. 913 at 15.

hypocrisy in embracing the opinions of their experts when it helps but avoiding them when it hurts. This approach extirpates the reliability of Holford’s so-called methodology, if any.

4. *Dr. Reed’s deposition testimony hurts, not helps, Holford.*

Defendants’ final point on Holford’s reanalysis of infection data also unravels his testimony. Dkt. No. 913 at 15–17. Defendants note that Dr. Reed “testified that there was an additional infection in both the Bair Hugger and HotDog groups,” *id.* at 15, yet they admit Holford did *not* rely on that testimony. *Id.* at 16. Other than footnoting Reed’s testimony,<sup>5</sup> Ex.C, Holford Rpt. at 3 n.1, Holford confessed to using “contradictory” data with “one fewer Bair Hugger infection.” *See* Ex.D, Holford Dep. at 173:5–9 (agreeing that his calculations contradict Reed’s sworn testimony). This fact alone dooms his testimony.

Mired in the web of contradictions throughout Holford’s analysis, Defendants only speculate about Dr. Reed’s statements. Dkt. No. 913 at 16. They “suggest” that Dr. Reed’s testimony was “not quite accurate” because it contradicts Exhibit 10. *Id.* But Holford has already destroyed the reliability of Exhibit 10. The same “written communication” that Defendants cite, moreover, reveals that the published data was “definitely correct” and that Dr. Reed had only asked Albrecht to analyze an “updated dataset”—flatly contradicting Defendants’ argument that this email thread demonstrates a tabulation error. *Cf.* Dkt. No. 913 at 16 (citing DX 17). Thus, Defendants’ reliance on *In re Viagra II* offers no assistance

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<sup>5</sup> Defendants wrongly suggest that Dr. Samet agreed that “Holford performed this analysis correctly.” *See* Dkt. No. 913 at 17. In so doing, Defendants not only admit that Holford relegated Dr. Reed’s testimony to “footnote 1,” but they misconstrue Dr. Samet’s opinion, which was limited to Holford’s “calculation,” not the inputs that he used therein. *Cf. id.*



because *Holford's* analysis, not the McGovern study, is plagued by “data discrepancies.” *Id.* at 18 (citing *In re Viagra Prods. Liab. Litig.*, 658 F. Supp. 2d 936, 945 (D. Minn. 2009)).

5. *Holford's reanalysis of infection data does not pass Rule 702.*

In the end, Holford's reanalysis unravels with the pull of a single thread. Holford admitted that he had no reason to rely on the incomplete data in Exhibit 10 instead of the final “raw case data” reported in the McGovern study. He simply cherry-picked data as he saw fit and relied on what Defendants spoon-fed him. *See In re TMI Litig.*, 193 F.3d at 705. Because Defendants have failed to show by a preponderance of evidence that Holford's methods are reliable, his opinions regarding an alleged “tabulation error” should be excluded. *In re Baycol Prods. Liab. Litig.*, 532 F. Supp. 2d 1029, 1042 (D. Minn. 2007); *see also Bailey*, 571 F.3d at 803 (“[E]xpert evidence is unreliable if it is speculative.”).<sup>6</sup>

**D. Holford Admits He Has No Basis to Fabricate an Alternative Start Date.**

The second aspect of Holford's opinion that Defendants at least attempt to defend is the “chosen start date” of the McGovern study. Dkt. No. 913 at 28–35. Hoping to distract the Court from his flawed methodology, they sweep all of his admissions under the rug and instead raise a potpourri of exhibits that were never cited or relied on by Holford. *See id.*

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<sup>6</sup> Defendants admit that Borak “relies on Holford's reanalysis,” Dkt. No. 913 at 5, but they do not attempt to defend it. Nor can they since an expert may not simply repeat or adopt the findings of another expert without attempting to assess the validity of those opinions. *See In re TMI Litig.*, 193 F.3d at 715–16 (declaring that blind reliance by expert on other expert opinions demonstrates flawed methodology under *Daubert*); *TK–7 Corp. v. Estate of Barbouti*, 993 F.2d 722, 732–33 (10th Cir. 1993) (excluding expert opinion relying on another expert's report because witness failed to demonstrate a basis for concluding report was reliable and showed no familiarity with methods and reasons underlying the hearsay).



Plaintiffs have already established that Holford fabricated his own start date for the McGovern study in order to calculate a non-significant increase in infection rates. Dkt. No. 802 at 20–21. Indeed, Holford testified that he relied on Exhibit 10 to establish an October 2007 start date even though Exhibit 10 was “not complete.” Ex.D, Holford Dep. at 247:14–21. Unable to disagree with Dr. Reed’s testimony that it would have been “very unreliable” to use data collected before July 1, 2008, Ex.G, Reed Dep. at 64:2–7, Holford likewise conceded that complete data was not available until that date or even until January 1, 2009. Ex.D, Holford Dep. at 247:4–13. Yet he *still* used data collected “prior to that time.” *Id.*

Outside the courtroom, Holford duly acknowledges the importance of collecting comprehensive data. Ex.R, Holford (2002). To do otherwise would allow unreliable results through “data artifact.” Ex.O, Holford (1992). Here, Holford violated his own methodology by reasoning backwards to select an unfounded start date, which allowed him to reach his desired results based on incomplete data. This “analytical gap” in his conclusions warrants exclusion of his testimony. *Junk v. Terminix Intern. Co.*, 628 F.3d 439, 448 (8th Cir. 2010).

Rather than address these glaring inconsistencies, Defendants cite two exhibits—Sprowson and unpublished McGovern manuscripts—that Holford *never* saw. Dkt. No. 913 at 28–32; *see* Ex.C, Holford Rpt. at 14; Ex.D, Holford Dep. at 93:11-94:15 (relying only on 19 sources); *see also Akeva v. Mizuno Corp.*, 212 F.R.D. 306, 310 (M.D.N.C. 2002) (“The Court cannot accept a definition of supplementation that would essentially allow for unlimited bolstering of expert opinions.”); *Beller v. United States*, 221 F.R.D. 689, 695 (D.N.M. 2003) (“To construe supplementation to apply whenever a party wants to bolster or submit additional expert opinions would [wreak] havoc in docket control and amount to

unlimited expert opinion preparation.”); *cf. Oklahoma v. Tyson Foods*, 2009 WL 2252129, at \*9 (N.D. Okla. July 24, 2009) (striking expert’s declaration since it was “nothing more than an effort to bolster his original opinion in order to stave off the *Daubert* challenge”).

Defendants then speculate that Dr. Reed “could access joint-infection data for primary joint arthroplasty patients prior to July 2008” because Sprowson reported similar data. *See* Dkt. No. 913 at 28. Nonsense. Dr. Reed swore that *he* could not obtain robust data prior to that date and that *he* was the only author able to do so. *See* Ex.G, Reed Dep. 46:11–20. Sprowson, moreover, analyzed “wound infection” rates, not DJI, from unnamed hospitals, not Wansbeck. DX24 at 21. And even if Dr. Reed “could” have collected data prior to the McGovern study despite his testimony, Dkt. No. 913 at 28, Holford *still* used unreliable data in creating his own start date. Ex.D, Holford Dep. at 111:2–4, 247:14–20.

Defendants finally speculate that “early drafts of the McGovern study suggest that the start date used in the published study was selected to achieve statistical significance,” even though they recognize that the authors did their best to “expand” rather than constrict the dataset. *See* Dkt. No. 913 at 29–32. Like the arguments before it, this argument also reflects nothing but innuendo and defense counsel’s ongoing campaign to “read the minds” of the authors to impute improper motives. Even a cursory review of the manuscripts shows the authors reported as much data as possible as long as the data were reliable. *Compare* DX25 (reporting data from 9/1/2008 to 9/1/2010), *with* Ex.B (reporting data from 7/1/08 to 1/1/2011). Their testimony also proves the point. Ex.EE, McGovern Dep. at 357:11–14.

Defendants cannot oppugn the study authors in the face of those undisputed facts. After all, it is Holford who ginned up an unfounded start date for the McGovern study, *not*

the authors of the study. *Cf.* Dkt. No. 913 at 29. Nor can Defendants cogently contend that “rising and falling infection rates” and misleading citations to the supposed “agenda” of the authors have any impact whatsoever on Holford’s testimony.<sup>7</sup> *See* Dkt. No. 913 at 28–31. Instead of following the pig trail of inadmissible evidence planted by Defendants, the Court should exclude Holford’s unreliable testimony regarding his fabricated “start date.”

### **III. HOLFORD AND BORAK VIOLATE BASIC SCIENTIFIC METHODS IN SPECULATING ABOUT HYPOTHETICAL CONFOUNDING FACTORS**

The only other testimony that Defendants even attempt to defend involves the fifth topic outlined *supra*—potential confounding factors. Epidemiologists follow a universally accepted methodology to identify potential confounding in observational studies: They look at existing scientific evidence to determine whether the *variable* is *meaningfully associated* with the *injury of interest* before identifying the variable as a confounder. *E.g.*, Ex.Z, Breslow at 105. Holford and Borak ignored this established method, instead using their own *ipse dixit* to identify changes to antibiotic, antithrombotic, and SSI interventions as potential confounders. This alone is grounds to exclude their opinions under *Daubert*.

#### **A. The Change in Antithrombotic Did Not Confound the McGovern study.**

Holford initially surmises that rivaroxaban (Xarelto), an antithrombotic drug administered to Bair Hugger patients, confounded the McGovern study. Ex.C, Holford Rpt.

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<sup>7</sup> Defendants cite a string of inadmissible exhibits for the proposition that that the “co-authors took great pains to ‘hide [the] agenda’ of their publication and to appear ‘impartial.’” Dkt. No. 913 at 34 n.17. For the sake of exposing Defendants’ ruse on the Court, not a single one of the cited exhibits reflects the McGovern study itself. *See* DX26 (presentation); DX27 (slide-show); DX28 (different authors discussing a different study).

at 5–6. Borak hinges his report on Holford’s analysis and thus shares the same opinion. *E.g.*, DX3 at ¶44; *cf.* Dkt. No. 913 at 10 (admitting that Borak relies on Holford’s analysis).

Holford cites a single study—Jensen (2011)—to support his opinion even though the study reached the *opposite* conclusion. *Cf.* Ex.C, Holford Rpt. at 5. The Jensen study compared DJI rates among patients who used rivaroxaban to patients who used tinzaparin—the same protocol as in the McGovern study. Ex.T. Contrary to Defendants’ arguments, Dkt. No. 913 at 19–21, Jensen did *not* find a meaningful difference in DJI rates among patients who used either regimen. Ex.T at 93. Since Jensen proves that DJI rates do not meaningfully vary in patients who use rivaroxaban or tinzaparin, the change in antithrombotic did not confound the McGovern study. *E.g.*, REFERENCE MANUAL at 595.

Holford admitted as much on cross-examination, averring that he had *no* support in the scientific literature to conclude that antithrombotic drugs have any impact on DJI rates:

Q: There is no published literature that you are aware of that suggests a relationship between the variable of a thromboprophylaxis on the outcome of deep joint infection.

A. **I don’t know of any.**

Ex.D, Holford Dep. 295:9–13 (emphasis added).

Avoiding Holford’s sworn admission, Defendants devote their entire argument to a rambling and myopic discussion of Jensen, even though they admit that coauthor Dr. Reed “couldn’t link rivaroxaban to infection.” Dkt. No. 913 at 19–23 (citing DX9, Reed. Dep. at 106:22–23). In so doing, they omit the undisputed fact that Jensen found no meaningful difference in DJI rates between rivaroxaban and tinzaparin. Ex.T at 93. They also fail to

confront Jameson (2012), which showed no difference in DJI rates between either antithrombotic regimen, Ex.Y at 1556, as noted by Holford, Borak, and the McGovern authors. Ex.G, Reed Dep. at 215:7–18 (ruling out rivaroxaban as a confounder). They even omit Holford’s own sworn admission that there is *not a scintilla* of evidence to suggest that rivaroxaban is, in fact, a confounder, along with his additional concession that his remixed calculations were *not* a “good estimate.” Ex.D, Holford Dep. at 219:1–23; 294:24-295:13.

While Holford and Borak cite *no* extant scientific evidence to establish an *a priori* relationship between rivaroxaban and DJI, Defendants conjure up a paper by Brimmo. Dkt. No. 913 at 23 (citing DX21). Even if Holford and Borak considered the study, *which they did not despite Rule 703*, it does not compare rivaroxaban to tinzaparin—the two drugs administered in McGovern. *See* DX21 at 1296. Nor did Brimmo compare the effect of either drug on 60-day DJI rates, as in McGovern; rather, it only considered the “incidence of *early* deep SSI.” *Id.* at 1295 (emphasis added). Brimmo is therefore inapposite, just as Defendants admit in attempting to address ancillary aspects of Plaintiffs’ argument. *See* Dkt. No. 913 at 22 (criticizing RECORD studies for failing to analyze tinzaparin); *see also id.* at 21 (criticizing Jensen study for using 30-day DJI rates instead of 60-day DJI rates).

In sum, sound scientific methodology required Holford and Borak to review reliable scientific studies to determine whether a suspected agent is associated with the outcome of interest before it can be identified as a confounder. Holford admitted he failed to do this in concluding that the change in antithrombotic regimen confounded the results of McGovern. His and Borak’s opinion, unhinged to facts, is entirely speculative and should be excluded. *See, e.g., Bailey*, 571 F.3d at 803 (“[E]xpert evidence is unreliable if it is speculative.”).

**B. The Change in Antibiotic Did Not Confound the McGovern study.**

Holford and Borak make the same methodological errors in opining that the change in antibiotic from gentamicin to gentamicin-plus-teicoplanin confounded the McGovern study. Notably, both reports fail to cite a *single* published study reporting a meaningful difference in DJI rates between those antibiotics, *see, e.g.*, Ex.C, Holford Rpt. at 6, thus defeating Defendants’ hyperbolic argument that “16 years” of “robust” evidence “strongly supports” Holford’s and Borak’s conclusions regarding confounding.<sup>8</sup> Dkt. No. 913 at 24.

Absent any published study to support their opinion, Defendants artificially attempt to distinguish Melling, which they admit found no benefit to using “prophylactic antibiotics [to] reduc[e] infection rates after clean surgery.” Dkt. No. 913 at 24. They also obfuscate Hickson (2015), which did not analyze DJI rates between gentamicin and gentamicin-plus-teicoplanin; nor did the “81 percent” reduction in “wound infection” touted by Defendants involve DJI. *See* Dkt. No. 913 at 25; *see also* Ex.BB, Hickson (2015) at 182. At bottom, Hickson found “no clear benefit to using one particular agent/regimen,” foreclosing Defendants’ argument regarding any hypothetical yet nonexistent confounding. *Id.* at 186.

Indeed, when confronted with Hickson’s conclusion that there is no known benefit to using gentamicin versus another antibiotic, Borak admitted he had *no* basis to dispute it:

Q. [D]irect your attention to the second paragraph down starting with “Although ...” It says, “Although there is a large body of evidence for the use of prophylactic antibiotics in primary hip and knee arthroplasty, there is

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<sup>8</sup> Defendants argue that “Plaintiffs ignore the robust evidence [allegedly showing] a clear benefit from the use of properly timed pre-incision prophylactic antibiotics.” Dkt. No. 913 at 24. This argument misses the point. The relevant inquiry is not whether antibiotics impact DJI, but whether changing from gentamicin to gentamicin-plus-teicoplanin did so.

no clear benefit to using one particular agent/regimen.”  
Do you see that?

A. I do.

Q. Okay. Do you have any reason to dispute the statements  
by Drs. Reed and Hickson as reported in this –

A. I –

Q. –article?

A. **I don’t.**

DX4, Borak Dep. at 193:19-194:7 (emphasis added).

Nor does the alleged absence of “evidence for the use of systemic gentamicin” save Holford or Borak, Dkt. No. 913 at 25, especially given Holford’s very own analysis, which shows that gentamicin yielded *lower* infection rates (1.92%) than when gentamicin was used *with* teicoplanin (3.13%). *See* Ex.C, Holford Rpt. at 6. Holford’s *own* calculation thus *disproves* his and Borak’s conclusion that gentamicin confounded the results of McGovern.

Professor Nachtsheim’s analysis of the McGovern data confirms that the change in antibiotic was *not* a confounder, but neither Defendants nor their experts *ever* mention it. Ex.F, Nachtsheim Dep. at 333:12-339:17, 349:22–23 (“I am *confident* that those weren’t confounding factors.”). In fact, Holford agrees that Nachtsheim is “an expert in the field of statistics,” yet he did *not* review Nachtsheim’s testimony. Ex.D, Holford Dep. at 87:8–14.

Never mentioning Nachtsheim’s analysis, Holford’s calculations, or Borak’s sworn admission, Defendants cling to Sprowson (2013). Dkt. No. 913 at 25–28 (citing DX24). Since Holford neither cited nor considered Sprowson, it cannot bolster his opinion. *See* Fed. R. Civ. P. 703. And while Borak cites the study, it fails to support his opinion. Like

every other study Borak cites, Sprowson did *not* analyze DJI at Wansbeck Hospital; rather, it evaluated all types of “wound infection” requiring “return to theatre,” including “[p]uncture of joint,” “[d]rainage of lesion of skin,” and “[o]ther operations.” DX24 at 21–22. So even if the “infection rate nearly tripled,” this is a red-herring. Dkt. No. 913 at 27.

Properly understood, Sprowson also compared the difference in “wound infection” rates of gentamicin to *cefuroxime*—an antibiotic that was *not* used in the McGovern study. DX24 at 20–23. Nor was the purpose of the study to evaluate *DJI* as in the McGovern study; rather it sought to determine whether gentamicin and cefuroxime impacted the rate of *clostridium difficile* associate with diarrhea (CDAD).<sup>9</sup> *Id.* at 21. Defendants thus use this irrelevant study as a smokescreen for only one reason: to distract the Court from the fatal flaws of Borak’s opinion. Because Borak’s and Holford’s opinions on antithrombotics and antibiotics fly in the face of the scientific literature and are untethered to any known scientific methodology for identifying confounding variables, they should be excluded.<sup>10</sup>

**C. Not a Shred of Evidence Shows that SSI Measures Are Associated with DJI.**

Holford’s and Borak’s opinions on “undisclosed confounders,” otherwise known as “SSI measures,” fail for the same reason as their other confounder theories. The pattern is identical, as both experts failed to identify a *single* study or scientific rationale for why a cornucopia of variables that have nothing to do with DJI would paradoxically impact DJI.

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<sup>9</sup> Defendants recognize as much, noting that Sprowson examined “wound infection” based on “another antibiotic” in order to ultimately evaluate “CDAD.” Dkt. No. 913 at 26–27.

<sup>10</sup> Defendants have not addressed Holford’s attempt to make the association between Bair Hugger and DJI “disappear” by controlling both variables—and for good reason. Holford failed to stand behind this “underpowered” calculation. Ex.D, Holford Dep. at 325:8-326:1.



When asked to explain the scientific basis of his “expert” opinion that SSI measures confounded the McGovern study, Holford literally responded that he just “assumed” they were; nor could he identify a single peer-reviewed study to support his rank speculation:

Q. Your – your report concludes that the SSI bundle may have had an effect on deep joint infection rates; correct?

A. Yes, the things that they were doing to control SSI may have had an effect.

Q. **You have no scientific basis to make that conclusion.**

A. **I’m – no, no. I’m just – just assuming that it does.**

Q. **Thank you. Do you know if any articles that you’re relying on relate to SSI versus DJI?**

A. **No.**

Ex.D, Holford Dep. at 308:5–17 (emphasis added). Borak fared no better, admitting he had failed to distinguish between SSI and DJI in his report.<sup>11</sup> DX4, Borak Dep. at 83:15-84:4. In fact, he readily conceded that he “bundled infections regardless of whether they were deep joint infections.” DX4, Borak Dep. at 204:9–15. He did so *despite* acknowledging the impropriety of conflating different types of infection. *Id.* at 201:17–21. Unsurprisingly, then, Defendants make no effort whatsoever to rehabilitate Borak’s unreliable opinion on “skin preparation” and other SSI measures. DX3, Borak Rpt. at 14; Dkt. No. 913 at 36–39.

Making no mention of those measures, Defendants fall back on Refaie (2015)—a discussion piece that did not present original research but cited raw data on MSSA

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<sup>11</sup> Defendants’ reliance on two online newsletters—Gillson (2014) and Brister (2011)—are likewise irrelevant because they discuss SSI instead of DJI. *See* Dkt. No. 913 at 36, 50.

screening. DX30. They also ignore the testimony of Dr. Reed, who coauthored Refaie and duly explained that it does *not* stand for the proposition that MSSA screening impacts DJI:

Q. [S]ome of the Bair Hugger patients at the very end have had MRSA screening and all of the Hot Dog only patients had the benefit of MSSA screening?

A. That is [tr]ue. But what I would say is that there is **no evidence that it reduces infection rates in this group.**

Ex.FF, Reed Dep. at 115:1–7; *id.* at 119:21–120:11 (testifying that there is “no evidence” that MSSA screening reduces “staph aureus infection rates in joint replacement patients”). Dr. McGovern agreed with Reed, concluding that the scientific literature does not support an association between MSSA screening and DJI. *See* Ex.H, McGovern Dep. at 409:4–8.

Unable to defend *any* of the SSI interventions actually cited by Borak, Defendants invent a new one out of whole cloth. Although *never* mentioned by Borak or Holford, Defendants unilaterally add a new “confounder” to the list—“prewarming.” Dkt. No. 913 at 37. Dr. McGovern, however, noted the dearth of evidence indicating that “pre-warming, when used in combination with intraoperative warming, significantly impacts deep joint infection rates.” Ex.H, McGovern Dep. at 409:9–14. Nor did Refaie find otherwise. *Cf.* Dkt. No. 913 at 37. While Refaie cited Melling for the proposition that prewarming reduces infection, that fact holds no weight here since *all* the patients in the McGovern study were warmed *intraoperatively*. Ex.FF, Reed Dep. at 117:25–118:9 (distinguishing Melling for the same reason). Nor has any published study found reduced DJI rates when patients receive prewarming *and* intraoperative warming. *E.g.*, Ex.H, McGovern Dep. at 409:9–14.

Finally, Defendants set up and knock down a strawman in surmising that Plaintiffs demand “statistically significant” proof of confounding. Dkt. No. 913 at 39. Far from it. Statistics aside, Holford and Borak must still have a scientific basis to show that a potential confounder is associated with the injury of interest (DJI). Both experts ignore this well-known rule despite the authorities cited in their *own* reports. Ex.C, Holford Rpt. at 8–9 n.14 (citing Breslow & Day); *see* Ex.Z, Breslow at 107 (“If a variable C is known from other studies to be related to disease . . . then C should be treated as a confounding variable.”).

Indeed, Holford and Borak have failed to identify *any* evidence to show *any* association between *any* SSI measure they cite and DJI. This is true for MSSA screening, Ex.FF, Reed Dep. at 115:1–8, as well every other measure, including wound dressings, *see* Ex.H, McGovern Dep. at 408:9-409:20; DX4, Borak Dep. at 158:4–8, and skin preparation, *id.* at 167:6–12. All these factors were thus “undisclosed” for an obvious reason: none of the authors or peer-reviewers had any reason to assert that they were, *in fact*, confounders.

Because their opinions rest on mere speculation and guesswork, not sound science, any testimony from Holford and Borak regarding “undisclosed” confounders should be excluded. Defendants have also wholly failed to respond to Plaintiffs’ arguments regarding Borak’s bizarre opinion about the “Hawthorne Effect” and his failure to use any recognized causation methodology.<sup>12</sup> Dkt. No. 779 at 20–22. Those opinions should be excluded too.

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<sup>12</sup> None of the points raised in Defendants’ Addendum save Borak’s opinion. For example, Defendants reiterate his arguments regarding the Hawthorne Effect but say nothing about his sworn admission that he had “no idea” if it applied. *See* DX4, Borak Dep. at 154:1–10.

#### IV. DEFENDANTS' LEGAL ARGUMENTS ARE SIMPLY SCARE TACTICS

Defendants' belated assault on the evidence in this multidistrict litigation mirrors the unsuccessful strategy of defense counsel in the PPA litigation. In a feeble attempt to distinguish the PPA decision, Defendants claim that the PPA study was "thoughtful," "objective" and "well-planned." Dkt. No. 913 at 39–43. But these were not the words used in that litigation. As here, defendants there argued that an epidemiologic study was poorly designed and so permeated with bias that when deconstructed, it showed no statistically increased risk of harm. *In re PPA Litig.*, 289 F. Supp. 2d. 1230, 1239 (W.D. Wash. 2003).

Defendants' rabid *ad hominem* attacks on the McGovern authors—and even the journal that reviewed the study—show the lengths they will go to discredit scientific work that threatens their products and profits. This vitriol is also evident in the inapposite cases they cite. They liken the well-credentialed McGovern authors<sup>13</sup> to the expert in *In re Viagra Prods. Liab. Litig.*, 658 F. Supp. 2d 936 (D. Minn. 2009). In that case, however, the court properly excluded the study because the expert had misclassified 40 percent of the patients in the study as being exposed rather than unexposed; the expert had also used a different statistical method than what he stated in his article. *Id.* at 942–44. Further, even *assuming* Holford correctly reclassified data in this case, which he did not, his analysis *still* shows more than a *doubling of the risk* as a result of Bair Hugger. This is not only sufficient to prove general causation, *but it proves specific causation by itself*. Dkt. No. 879 at 36–38.

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<sup>13</sup> Professor Nachtsheim, for example, is a statistics professor at the Carlson School of Management who became a Fellow of The American Statistical Association (the highest honorary grade of membership) long before Holford. *See* Ex.D, Holford Dep. at 87:2–4. Holford thus considers Professor Nachtsheim to hold "expertise" in statistics. *Id.* at 8–11.

Nor is this case anything like the unreported decision in *Palazzolo v. Hoffman La Roche*, 2010 WL 363834 (N.J. App. Feb. 3, 2010). In that troublesome case, the expert did not follow the same methodology he described in his study; he did not obtain patient questionnaires as stated in the study; and he relied on scientific evidence that actually showed no differences in the brains of the exposed versus non-exposed groups. *Id.* at \*4.

Defendants even go so far as citing another unpublished decision, *Cedillo v. Sec’y of Health & Human Servs.*, 2009 WL 331968 (Fed. Cl. Feb. 12, 2009), to accuse the McGovern authors of committing “scientific fraud.”<sup>14</sup> In that litigation, though, the lead author of a small, non-epidemiologic study overstated its conclusions, prompting his co-authors to retract their causation opinions; the editors of the journal, in fact, also retracted the article for not disclosing that the subjects were parties in the litigation. *See id.* at \*110.

Because all these cases concern facially unreliable research, they stand in stark contrast to the McGovern study, which has never been retracted—indeed, no one has even called for its withdrawal—and whose authors continue to stand by the veracity of its findings. In the final analysis, these histrionic attacks reflect poorly on Defendants and cast a shadow over Holford and Borak. Allowing Defendants to mislead them by the nose and spoon-feed them inaccurate and incomplete information renders their opinions unreliable. The Court should exclude such testimony and disabuse Defendants of their scare tactics.

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<sup>14</sup> Unlike Defendants’ baseless argument, their own experts refused to level the same false polemic; nor could they even explain the basis for Defendants’ unfounded invective that the McGovern authors engaged in “data manipulation,” much less “scientific fraud.” *See, e.g.,* DX4, Borak Dep. at 227:13-228:18 (unable to accuse any author of similar conduct).

## V. CONCLUSION

In sum, the Court should exclude Holford and Borak because their opinions are unreliable, speculative, and irrelevant under the Federal and Minnesota Rules of Evidence.

Respectfully submitted,

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